

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

<i>In Re</i> Flint Water Cases	No. 5:16-cv-10444-JEL-MKM Consolidated HON. JUDITH E. LEVY MAG. MONA K. MAJZOUB
Anderson, et al., <i>Plaintiffs,</i> v. City of Flint, Michigan, et al., <i>Defendants.</i>	No. 5:17-cv-13890-JEL-MKM

***ANDERSON* PLAINTIFFS' BRIEF IN OPPOSITION TO CO-LIAISON
COUNSEL'S BRIEF IN SUPPORT OF FINAL APPROVAL OF THE
PROPOSED SETTLEMENT**

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CONCISE STATEMENT OF THE ISSUES PRESENTED

1. Whether the Proposed Partial Settlement Agreement should be approved by this Court as there are unresolved issues of safety and an ongoing investigation by the MIOSHA/Radiation Safety Department?
2. Whether the City of Flint's water distribution system has exposed every household, business, and visitor to the city to lead contamination which is being addressed by the proposed partial settlement agreement, or, does the proposed partial settlement agreement impose additional hurdles to appropriate compensation, requiring rejection?

CONTROLLING OR MOST APPROPRIATE AUTHORITY

- Federal Rule of Civil Procedure 23
- Title 21 U.S.C § 321(h)
- Title 21 U.S.C. § 331
- Mich. Admin. Code R333.5023
- Mich. Admin. Code R333.5036
- Mich. Admin. Code R333.5037
- Mich. Admin. Code R333.5047
- MCL § 333.2262
- *Franks v Kroger Co.* 649 F. 2d 1216 (6th Cir. 1981)
- *International Union, United Automobile, Aerospace, & Agricultural Implement Workers of America v. General Motors Corp.*, 497 F.3d 615, (2007)
- *Williams v Vukovich*, 720 F. 2d 909 (6th Cir. 1983)
- *Gen. Tel. Co. of SW. v Falcon* 457 U.S. 147, 102 S. Ct. 2364 (1982)

I. INTRODUCTION

The *Anderson* Plaintiffs object to the proposed partial settlement agreement because its methodology and proposed implementation impose additional unnecessary barriers to compensation on the Flint, Michigan community that has already been traumatized by its state government.

ECF 1795, PageID.64470, Co-Liaison Counsel’s Brief in Support of Final Approval of the Proposed Settlement states that, a hybrid structure has been established “that includes both a Class Action component and an individual (“non-class”) traditional mass tort settlement that is triggered by a participation rate methodology.” ECF 1795, PageID.64474.

The proposed partial settlement agreement requires the Court to treat both class members and individual plaintiffs in a “fair and reasonable manner.” The proposed “participation rate methodology” does not offer fair and reasonable treatment to all injured parties, nor does it provide for equal access to fair compensation.

The Bone Lead Scanning component of the proposed partial settlement agreement, is the primary focus of the *Anderson* Plaintiffs’ continuing objection to its inclusion in the settlement methodology. In addition, the Individualized Education Program (IEP) criteria in the proposed settlement agreement uses a

standard which exceeds the regulations of State and Federal authorities. ECF No. 1436, PageID.55040-55044.

II. ARGUMENT

A. THE OBJECTIONS OF THE INDIVIDUAL CLAIMANTS ARE VALID

The debate over the safety issue of Bone Lead Testing is ongoing, and has proponents on either side, making the approval of the test results inappropriate for inclusion in the proposed settlement agreement. Safety is undetermined now, and into the future.

Since the filing of the Master Settlement Agreement (MSA) on November 17, 2020 ECF No. 1319-1 and the Amended Master Settlement Agreement (“AMSA”) on January 15, 2021, ECF No. 1393-2 there have been ongoing investigations by the individual claimants into several major aspects of the X-Ray Fluorescence (XRF) bone lead testing program (hereinafter the “Program”).

1. Unknown Safety of the Device – *in vivo* Testing

Dr. Lawrence A. Reynolds, a Board-Certified Flint Pediatrician, filed the first objection to the Program’s use of XRF technology on February 26, 2021 ECF No. 1436, PageID.55021. Dr. Reynolds stated:

XRF is the acronym for X-ray fluorescence. As the name suggests, it is an X-ray. In a medical setting, limiting exposure to X-rays is required and X-rays should only be done if medically necessary - especially in the case of infants and children. Use of this unapproved industrial device to perform a bone scan on live humans in the settlement process as is being done, is at best, unauthorized research. It is neither a part of an approved diagnostic procedure, nor a proven beneficial treatment protocol, especially for children. It is not an approved practice by any global regulatory agency or professional body. It is being promoted by misinformed attorneys, for an undisclosed research project, not licensed medical practitioners. The XRF hand held device is not designed to be used on human beings – at all. It presents the risks of exposure to radiation without the benefit of any information that would change the mitigation interventions for the lead poisoned child or adult. ECF No. 1436 PageID.55026-55027.

Dr. Reynolds' February 2021 concerns, were validated when ThermoFisher Scientific (hereinafter "TFS"), the manufacturer of the Niton™XL3t 950 GOLDD+ XRF analyzer (hereinafter the "XL3t") being used in the Program, issued a letter, from Chloe Hansen-Toone, Vice President and General Manager, on May 12, 2021 to Barbara Krohmer, at Napoli Shkolnik & Assoc., PLLC, 400 Broadhollow Rd. Ste. 305, Melville, NY 11747. **See Exhibit A.** Vice President and General Manager Hansen-Toone advised Ms. Krohmer:

...We have recently learned that Napoli, working in conjunction with Dr. Aaron Specht may have been using its XL3t in a manner inconsistent with the use for which Thermo Fisher markets the XL3t... we believe that Napoli and/or Dr. Specht may have used the XL3t on human subjects, in an effort to analyze said subjects' levels of lead exposure.

As such, we write to advise you that Thermo Fisher has never marketed the XL3t for any *in vivo* diagnostic use (including, without limitation, any such use to measure bone lead levels in living persons,) nor have we sought or obtained FDA approval for such use...Your use of the XL3t

does not appear to arise in the context of academic research, and we are not aware of any IRB approval for your activities.

As you are aware, in your rental agreement with Thermo Fisher, Napoli agreed to be “solely responsible for the safe and prudent operation of” the XL3t. The safety instructions contained in the XL3t User’s Guide explicitly instruct all users to “[n]ever point your analyzer at yourself or anyone else when the shutter is open.” All users are expected to abide by these safety instructions, except under specific circumstances (not present here) that create adequate assurances regarding safety. We further advise you that Thermo Fisher has not validated the safety of the XL3t when used in a manner inconsistent with its safety instructions.

TFS’ “XRF technology in the field, XRF technology for non-scientists states at page 19, “Did you know? While the radiation emitted from a portable XRF analyzer is similar to the exposure received in a normal medical or dental X-ray, care must be taken to always point a handheld XRF analyzer at the sample and never at a person or a body part.” **See Exhibit B.**

Thirteen (13) days after his law firm received Vice President and General Manager, Hansen-Toone’s May 12, 2021 letter Attorney Paul Napoli filed a Declaration with the Court on May 25, 2021, ECF No.1786-7, PageID.63899, in which Attorney Paul Napoli stated:

4. ... The program uses a non-invasive portable X-Ray fluorescence scanning device to safely and accurately detect bone lead levels.
6. ...The XRF scan poses no risk to children or adults...

11. I emphasize that under no circumstances would we ever expose our clients or others in the community to risk of harm...The XRF program in Flint is implemented with health and safety as the highest priority and is a safe and accurate means of measuring long-term lead exposure.
See Exhibit C.

Mr. Napoli's Declaration did not disclose the following:

1. That the objections of TFS for the use of its XL3t device for *in vivo* testing were still in place;
2. That there was an ongoing investigation by the MIOSHA Radiation Safety office of the Program facility based upon a formal complaint by Dr. Lawrence A. Reynolds from March 17, 2021; ***See Exhibit D – June 11, 2021 Email from Renee Kugler (LEO) – Formal Complaint from Dr. Lawrence A. Reynolds, M.D., FAAP.***
3. That the Registration Certification with the State of Michigan became effective on March 1, 2021; ***See Exhibit E – Radiation Machine Registration No. FAC-REG-21-038092.***
4. That the Program had been testing Flint residents for a period of time which pre-dated March 1, 2021, and the public announcement of the Proposed Settlement Agreement;

5. That Michigan Administrative Rule R333.5037 required a person with one (1) or more radiation machines to apply for registration of the machine with the department of radiation safety before using the machine;
6. That Michigan Administrative Rule R333.5047 required a person bringing a radiation machine into the State of Michigan must register the machine with the department of radiation safety and comply with all of the applicable rule of the department;
7. That the program had failed to supply a radiation shielding plan to the department of radiation safety for its mobile/portable radiographic machine that was going to be routinely used at its Flushing Road location as required by Michigan Administrative Rule R333.5036; and,
8. That Michigan Administrative Rule R333.5023 provided that a violation of a radiation machine rule could subject the violator to civil and criminal penalties. ***See Exhibit F – Regulations and Statutes governing the use of Radiation Machines in Michigan.***

Without the results of the ongoing investigation by the MIOSHA/Radiation Safety Section it is impossible to know exactly how many regulations were violated by the “Program,” but it appears that there was at a minimum a failure to register an out-of-state X-ray portable device brought into the State of Michigan - R333.5047;

failure to submit a shielding plan for review before using the machine – R333.5036; and, failure to register the portable radiation machine before using the machine – R333.5023, and MCL § 333.2262.

The unfortunate part of this aspect of the Bone Lead Level Scan testing program, is that approval is being sought now, for the payment of hundreds of millions of dollars, in compensation to injured Flint residents without complete information being provided to the Court.

On May 27, 2021 Dr. Aaron Specht filed an affidavit, ECF No. 1795-2, PageID.64490, within which he stated that he received a certification in Medical Physics from the American Board of Radiology in 2013 ECF No. 1795-2, PageID.64497. The American Board of Radiology only lists certification status for physicians, which did not include Dr. Aaron Specht, PhD. **See Exhibit G.**

2. Diagnosis or Not?

Mr. Napoli stated in his Declaration, ECF No. 1786-7, at PageID.63900 that:

5. The purpose of the XRF program is solely to determine individual bone lead levels. These scans were not, and are not, being used to *diagnose* or treat any medical condition. *The test's sole purpose here is to help quantify lead exposure.* Moreover, it can assist in understanding the levels of lead in Flint residents who were otherwise told not to seek blood lead tests at the height of their exposure half a decade ago. The measurements are used for litigation purposes only, including as part of the settlement with several defendants including the State of Michigan – to provide one avenue of ensuring an

individual receives fair and just compensation for the full extent of their exposure.

On March 5, 2021 Co-Liaison Counsel, Corey Stern, and Hunter Shkolnik, sent a joint letter to the chambers of Judge Levy, which was then placed into the Court ECF system at ECF No. 1455, PageID.57127. **See Exhibit H.** In Exhibit H, *supra*, Mr. Stern and Mr. Shkolnik stated,

...Similarly, approval is not required under the Food, Drug, and Cosmetic Act (“FDCA”) because the XRF scans in Flint are not intended for use in the *diagnosis of disease or other conditions...*” The tests are not being used to inform the recipient of any medical or *diagnostic* criteria beyond the test results itself for purposes of litigation and claim categorization...PageID.57130.

The definition of “Diagnosis – Definition by Medical Dictionaries, attached as **Exhibit I** revealed the following example definitions of “diagnosis:”

“The determination of the nature of a ...*injury*...” Farlex Partner Medical Dictionary© Farlex 2012.

“The act or process of identifying or determining the nature ... of a ...*injury* through...examination...” The American Heritage® Medical Dictionary Copyright © 2007, 2004 by Houghton Mifflin Company. Published by Houghton Mifflin Company. All rights reserved.

“The determination of the nature of a ...*injury*...” Medical Dictionary for Health Professions and Nursing © Farlex 2012.

“identification of a particular *pathological...condition*...” Collins Dictionary of Biology, 3rd ed. © W.G. Hale, V.A. Saunders, J.P. Margham 2005.

“The determination of the nature of a...*injury*...” Medical Dictionary for the Dental Professions © Farlex 2012.

Dr. Specht in his May 27, 2021 affidavit, ECF No. 1795-2, PageID.64494 stated:

12. ...Similarly, approval is not required under the Food, Drug, and Cosmetic Act (“FDCA”) because the XRF scans in Flint are *not* “intended for use in the *diagnosis* of disease *or other conditions*...” The test is not being used to inform any medical or diagnostic criteria beyond the test results itself for purposes of litigation.

The nature of the injuries in the present case are determined by the question of whether individual plaintiffs were exposed to lead contamination. The Program Managers are using the XL3t device to determine just that, the nature of lead contamination injuries present in plaintiffs’ bones. The use in this case clearly falls within the “diagnosis” definitions above.

The repeated statement by program managers is that the purpose of the testing was to quantify the amount of lead in a person’s body for purposes of the litigation. Program managers are seeking tens of thousands of dollars of additional compensation for their clients with positive bone lead results, yet denying that the test was used to diagnose “injury.”

Further, absent from any statements from program managers is any type of prior approval, or current approval letter from the Food and Drug Administration which exempted the Flint Program from FDA approval. TFS did not pursue FDA

approval for its XL3t for *in vivo* use as it was never intended for *in vivo* use, and TFS explicitly stated as much in its May 12, 2021 letter.

III. CONFLICT OF INTEREST

The proposed partial settlement agreement requires equal treatment of class members and individual plaintiffs. However, this agreement allows for disparate treatment.

Fed. R. Civ. P. 23(g)(B) provides in pertinent part:

(g) CLASS COUNSEL. (1)Appointing Class Counsel. Unless a statute provides otherwise, a court that certifies a class must appoint class counsel. In appointing class counsel, the court: **(A)** must consider: ...**(B)** may consider any other matter pertinent to counsel's ability to fairly and adequately represent the interests of the class;...

The United States Supreme Court noted in *Gen. Tel. Co. of Sw. v Falcon*, 457 U.S. 147, 102 S. Ct. 2364 (1982), that the adequacy of representation requirement of class representatives tended to merge the concerns of competency of class counsel and conflicts of interest:

The commonality and typicality requirements of Rule 23(a) tend to merge. Both serve as guideposts for determining whether under the particular circumstances maintenance of a class action is economical and whether the named plaintiff's claim and the class claims are so interrelated that the interests of the class members will be fairly and adequately protected in their absence. Those requirements therefore also tend to merge with the adequacy-of-representation requirement, although the latter requirement also raises concerns about the competency of class counsel and conflicts of interest. *Gen. Tel. Co. of Sw. v. Falcon*, 457 U.S. at 158 n.13 (1982).

The Sixth Circuit adopted note 13 in the case of *International Union, United Automobile, Aerospace, & Agricultural Implement Workers of America v. General Motors Corp.*, 497 F.3d 615, (2007) when it stated:

Because named class members must act through class counsel, adequacy of representation turns in part on "the competency of class counsel" and in part on the absence of "conflicts of interest." *Gen. Tel. Co. of Sw. v. Falcon*, 457 U.S. 147, 157 n. 13, 102 S.Ct. 2364, 72 L.Ed.2d 740 (1982); *see* Fed.R.Civ.P. 23(g)(1)(C). *International Union, United Automobile, Aerospace, & Agricultural Implement Workers of America v. General Motors Corp.*, 497 F.3d at 626.

Here, Co-Liaison Counsel were appointed pursuant to ECF No. 234, PageID.8721 which required them to "Generally act fairly, efficiently, and economically in the interests of all parties and parties' counsel...Keep the other plaintiffs' counsel advised of the progress of the litigation and consult them about decisions significantly affecting their clients..." PageID.8725 – 8726.

It is the position of the *Anderson* Plaintiffs that the Conflict of Interest of Co-Liaison Counsel arose from the following actions:

1. Negotiated a partial settlement agreement that prioritized the use of technology that only they controlled.
2. They began bone lead level testing on their clients before the Master Settlement Agreement was publicly announced.

3. They put in the agreement other compensation methods which contained burdens of proof that exceeded State and Federal regulations for IEPs.
4. They put in the agreement the use of “real time” blood lead level test results that would have to have been taken at a time with the State of Michigan was telling Flint residents that there was nothing wrong with their water.
5. When Class Counsel attempted to set up a parallel testing site Co-Liaison Counsel refused to grant access to their testing protocols. *See Exhibit J - Affidavit of Andrew Christian Todd, Ph.D. and Karl John Jepsen, Ph.D., ECF No. 1497, PageID.58184.*

IV. Inference of Academic Approval

Program Managers placed the Harvard and New York University (NYU) logos on their test result sheets, implying that they were working with or under the auspices of those institutions. When NYU’s office General Counsel was advised of the use, Associate General Counsel, Eric Pollex Rasmussen stated:

Dear Mr. Cuker, thank you for bringing this matter to our attention. Dr. Weitzman confirmed that, in connection with his consulting with plaintiffs in the litigation, he is not acting on behalf of NYU. He stated he will remove the use of NYU’s name and logo from reports issued in his name. **Exhibit K – June 21, 2021 email from Associate General Counsel, Eric Pollex Rasmussen to Attorney Mark Cuker, sent 2:40 PM.**

V. Lack of Regulatory Compliance

The Napoli Flint Program received its Registration Certificate on March 1, 2021, however Michigan Administrative Rule R333.5037 requires registration of each machine “*before operating the machine.*” Upon information and belief, the Napoli Flint Program was conducting bone lead scans before March 1, 2021. Under MCL § 333.2262:

- (2) Under the authority of MCL 333.2262, the department, in addition to taking other enforcement action, may impose a civil penalty, not to exceed \$1,000 for each violation, on a person who violates the act, a rule, an order, or a registration condition issued under the act. Each day that a violation continues shall constitute a separate violation.
- (3) A person who violates the act, a rule, an order, or a registration condition issued under the act ***may be guilty of a misdemeanor*** and, on conviction, may be fined, imprisoned, or both, as provided by law. Exhibit Q, *supra*.

The Food, Drug & Cosmetic Act, Title 21 U.S.C. § 321(h) provides in pertinent part regarding “medical devices:”

The FD&C Act generally defines the term "device" as "an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessory, which is - ... (2) intended for use in the *diagnosis* of disease or *other conditions*, ...*Id.* § 321(h).

Based on the multiple statements of Mr. Napoli, Mr. Shkolnik, and Mr. Stern the Flint Napoli Program made no effort to seek the approval of the Food and Drug

Administration before starting their bone scans in Flint, an apparent violation of Title 21 U.S.C. § 331:

- (a) The introduction or delivery for introduction into interstate commerce of any food, drug, *device*, tobacco product, or cosmetic that is adulterated or misbranded.
- (b) The adulteration or misbranding of any food, drug, *device*, tobacco product, or cosmetic in interstate commerce.
- (c) The receipt in interstate commerce of any food, drug, *device*, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise. 21 U.S.C. § 331(a) – (c). Emphasis added.

Whether the “calibration” admitted to by Dr. Specht in his Affidavit, ECF No. 1795-2, PageID.64491, is considered an adulteration of the “Device” is beyond the scope of the Motion for Approval of the Proposed Settlement, however, at the very least the Court should seriously consider whether it wants to approve a settlement within which components may have been utilized/operated in violation of Federal or State laws. Due to the time constraints now in place it simply isn’t feasible to wait for the results of the MIOSHA Radiation Safety investigation or to refer this matter to the FDA.

In *Williams v Vukovich*, 720 F. 2d 909, (1983) an employment discrimination case the Sixth Circuit cautioned,

The court should insure that the interests of counsel and the named plaintiffs are not unjustifiably advanced at the expense of unnamed class members. *See Plummer*, 668 F.2d at 660; *Franks v. Kroger Co.*, 649 F.2d 1216, 1225 (6th Cir. 1981), *vacated*, 670 F.2d 71 (1982).

Objections raised by members of the plaintiff class should be carefully considered. *Williams v. Vukovich*, 720 F.2d at 923.

The Consent Decree entered by the trial court was reversed and vacated when it found that, “The Final Decree is illegal and contrary to the public interest.” *Id.* at 925.

Here, there is no Final Consent Decree to be ruled upon, however the proposed Settlement Agreement will bind the interests of both class and individual plaintiffs, and as such, the competing public interests must be considered by this Court.

SUMMARY

It is the position of the *Anderson* Plaintiffs that the following actions/points should be carefully considered by the Court as a part of its final decision regarding approval of the proposed settlement agreement:

1. TFS’ statement that its XL3t device was not manufactured nor approved by it for use on humans.
2. That there is an ongoing investigation into the program by MIOSHA/Radiation Safety Department.
3. Lack of access to all plaintiffs to the Bone Scan Testing.
4. The use of the device before registering it with the State of Michigan.
5. The improper inference that the Program had been approved by NYU.

In as much as the Court does not have the authority to modify the proposed partial settlement agreement, which by its terms has imposed additional traumatic hurdles to get fair and reasonable compensation, the question to be answered is, should the actions of the lawyers described herein be approved by the Court?

CONCLUSION

This Court has only two choices related to the proposed settlement agreement, to approve it, or to not approve it. In light of the irregularities described above the *Anderson* Plaintiffs respectfully request the Court to disapprove the proposed settlement agreement as submitted.

Dated: June 24, 2021

Respectfully submitted,

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